HFT-35 m32391

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Cincinnati District Office
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
FAX: (513) 679-2772

WARNING LETTER

Cin WL 916-0

December 8, 1999

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Fred Jackson
Chief Executive Officer
King's Daughters' Health Park at Cedar Knoll
10650 U.S. Route 60
Ashland, KY 41102

Facility I.D.#: 220826

Dear Mr.Jackson:

A representative from the Commonwealth of Kentucky radiation control program under contract to the Food and Drug Administration inspected your facility on November 4, 1999. This inspection revealed that your facility failed to comply with the Quality Standards for Mammography (Standards) as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

> Your facility phantom quality control records were missing for six weeks for your facility mammography unit. Mammograms were performed on patients during these six weeks without the required weekly phantom film checks on the mammography units.

The specific deficiency noted above appeared under the Level 1 heading on your MQSA Facility Inspection Report, which was issued at the close of the inspection. This deficiency may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility.

In addition, your response should address the Level 2 noncompliance items that was listed on the inspection report provided to you at the close of the inspection. These Level 2 noncompliance items are:

> 1. Your mammography processor was found to have a processing speed of 65 optical density unit for standard processing cycle. The MQSA requirement is the mammography processor operates in the range of 80-120 optical density units.
>
> 2. Your records did not demonstrate that your facility performed corrective actions for failures of the phantom image score as part of the mammography phantom quality control checks.

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA's regulations. You are responsible for investigating and determining the causes of the deficiencies that the inspection identifies and promptly initiate permanent corrective actions.

If you fail to promptly correct these deficiencies, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may:

- Impose civil money penalties on a facility of up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards.
- Suspend or revoke a facility's FDA certificate for failure to comply with the Standards.
- Seek an injunction in federal court to prohibit any mammography activity that constitutes a serious risk to human health.

Within 15 working days after receiving this letter, you should notify FDA in writing of:

- The specific steps you have taken to correct all of the violations noted in this letter;
- Each step your facility is taking to prevent the recurrence of similar violations;
- Sample records that demonstrate proper record keeping procedures related to quality control.

If your facility is unable to complete the corrective action within 15 working days, you should state the reason for the delay and the time within which the corrections will be completed.

Please send the original copy of your response to:

R. Terry Bolen
MQSA Compliance Officer
Food and Drug Administration
6751 Steger Dr.
Cincinnati, OH 45237-3097

Also, please send a copy to the State radiation control office:

Ms. Julie Keightley
Commonwealth of Kentucky
Cabinet for Human Resources
Department for Health Services
Radiation Producing Machines & Operator Certification
275 East Main St.
Frankfort, KY 40621

If you have any questions regarding this letter or how to ensure you are meeting MQSA standards, please call R. Terry Bolen at (513) 679-2700, extension 138.

Sincerely yours,

Henry L. Fielden
District Director
Cincinnati District Office

c.
KY/JKeightley